EXHIBIT A

WALLACH EXHIBIT A

Name	Case Number
Larson, Naomi & Mark	2:14cv22872

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***All Wave 13 Cases***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

GENERAL RETAINED EXPERTS

1) Dr. Bruce Rosenzweig (Urogynecologist) (adoption of previously served reports)
Rush University Professional Building
1725 West Harrison Street, Suite 358
Chicago, IL 60612

2) Dr. Daniel Elliott (Urologist) (adoption of previously served reports)
Mayo Clinic
200 1st Street SW
Rochester, MN 55902

3) Dr. Jerry Blaivas (Urologist) (adoption of previously served reports)
445 East 77th Street
New York, NY 10075

4) Dr. Ralph Zipper (Urogynecologist) (adoption of previously served reports)
Zipper Urogynecology
1130 S. Harbor City Boulevard
Melbourne, FL 32901

5) Dr. Robert Shull (Urogynecologist) (adoption of previously served report)
Scott & White Clinic & Hospital
Department of Obstetrics and Gynecology
2401 S. 31st Street
Temple, Texas 76508

6) Dr. Abbas Shobeiri (Urogyn)
500 North Washington St
300
Falls Church, VA 22046

7) Dr. Vladimir Iakovlev, M.D. (Pathologist) (adoption of previously served report)
St. Michael's Hospital, Division of Pathology
30 Bond Street, Cardinal Carter, Room 2-093
Toronto, ON, M5B1W8
CANADA

8) Dr. Paul Michaels (Pathologist) (adoption of previously served report)
Austin, TX

9) Prof. Dr. med. Uwe Klinge (Materials) (adoption of previously served report)
KLINIK FÜR ALLGEMEIN-, VISZERAL- UND
TRANSPLANTATIONSCHIRURGIE
RWTH Aachen und Universitätsklinikum Aachen
Pauwelsstraße 30
D-52074 Aachen
Germany

10) Prof. Dr.-Ing. Thomas Muehl (Materials) (adoption of previously served report)
FH Aachen - University of Applied Sciences
Labor für Elektrische Messtechnik und Prozessdatenverarbeitung
Eupener Str. 70
52066 Aachen
Germany

11) Dr. Howard Jordi (Materials) (adoption of previously served report)
Jordi Labs
200 Gilbert Street
Mansfield, MA 02048

12) Dr. Scott Guelcher (Materials) (adoption of previously served report)
Polymer and Chemical Technologies, LLC
1008 Caldwell Avenue
Nashville, TN 37204

13) Dr. Jimmy Mays (Materials) (adoption of previously served report)
Department of Chemistry
University of Tennessee at Knoxville
655 Buehler Hall
Knoxville, TN 37996

14) Dr. Dionysios Veronikis (Urogyn) (adoption of previously served report)
St. Johns Mercy Medical Center
Tower B
621 S New Ballas Rd
#2002-B
St. Louis, MO 63141

15) Dr. Michael Thomas Margolis (Urogyn) (adoption of previously served report)
Bay Area Pelvic Surgery
1820 Ogden Dr.
Burlingame, California 94010

16) Dr. Anne Wilson (FMEA) (adoption of previously served report)
QA Consulting, Inc.
7500 Rialto Blvd.
Bldg. 1, Ste. 225
Austin, Tx 78735

17) Dr. John Miklos (Urogyn) (adoption of previously served report)
3400 Old Milton Parkway
Bldg. C, Suite 330
Alpharetta, GA 30005

18) Dr. Neeraj Kohli (Urogyn) (adoption of previously served report)
70 Walnut St
Wellesley, MA 02481

19) Dr. Alan Garely (Urogyn) (adoption of previously served report)
1 S Central Ave
Valley Stream, NY 11580

20) Dr. Brian Raybon (Urogyn)
79 Doyle St
Toccoa, GA 30577

21) Dr. Robert Moore (Urogyn) (adoption of previously served report)
3400 Old Milton Pkwy
Alpharetta, GA 30005

22) Dr. Donald R. Ostergard (Urogyn) (adoption of previously served report)
8557 Mountain View Farms Ln
Salida, CO 81201

23) Duane Priddy, Ph.D. (Materials) (adoption of previously served report)
Plastic Failure Labs
6004 Camelot Ct
Midland, MI 48640

24) Dr. Anne M. Weber (Urogynecologist) (adoption of previously served report)
5626 Sharon Drive
Glen Arm, MD 21057

GENERAL RETAINED REGULATORY EXPERTS

Plaintiffs recognize that the Fourth Circuit has affirmed Judge Goodwin's decision to exclude evidence relating to a manufacturer's compliance with the FDA's 510(k) process. In the event of a contrary ruling, Plaintiffs reserve the right to designate the following General Regulatory Experts:

1) Dr. Peggy Pence (Regulatory) (adoption of previously served reports)
Symbion Research International, Inc.
3537 Old Conejo Road, Suite 115
Newbury Park, CA 91320

2) Dr. Suzanne Parisian (Regulatory) (adoption of previously served report)
MD Assist, Inc.
7117 N. 3rd Street
Phoenix, AZ 85020

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02326** **MDL No. 2326**
THIS DOCUMENT RELATES TO: ***Naomi Larson, et al. v Ethicon, Inc., et al.*** **Case No. 2:14-cv-22872**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFF'S DESIGNATION AND DISCLOSURE OF GENERAL AND CASE-SPECIFIC EXPERT WITNESSES

Pursuant to Pretrial Order (PTO) #346, Rule 26(a)(2) of the Federal Rules of Civil Procedure, Plaintiff in the above-captioned civil action ("Plaintiff") submits the following Designation and Disclosure of General and Case-Specific Expert Witnesses and persons who may provide expert testimony specific to Plaintiff's case pursuant to Rule 702 of the Federal Rules of Evidence.

RETAINED EXPERT WITNESSES

1. Stacey J Wallach, M.D.
   University of California, Davis School of Medicine
   4860 Y Street, Suite 2500
   Sacramento, CA 95817

2. Dr. Alan Garely
   1 S Central Ave
   Valley Stream, NY 11580

3. Dan Elliot, MD
   Mayo Clinic
   200 1st Street, SW
   Rochester, MN

4. Dr. Brian Raybon
   79 Doyle St
   Toccoa, GA 30577

5. Prof. Dr. med. Uwe Klinge
   KLINIK FÜR ALLGEMEIN-, VISZERAL- UND TRANSPLANTATIONSCHIRURGIE
   RWTH Aachen und Universitätsklinikum Aachen
   Pauwelsstraße 30
   D-52074 Aachen
   Germany

A General Designation and Disclosure has been or is being served by and on behalf of the Ethicon Wave 13 cases for general expert opinions. In the event that any of the general expert(s) identified above is/are unavailable for trial in this case, Plaintiff reserves the right to elicit testimony, either through direct examination or cross-examination, of other of the general witnesses designated or identified by Plaintiff. In no event, however, will Plaintiff's retained experts at trial exceed five (5) experts without leave of Court for good cause shown. Plaintiff further reserves the right, as allowed by Rule 26(e) of the Federal Rules of Civil Procedure, to supplement this Designation and Disclosure of Expert Witnesses through the discovery process upon receiving additional discovery including, but not limited to, expert depositions, fact depositions, exhibits introduced in depositions, documents produced, and any supplemental disclosures by any party.

GENERAL RETAINED REGULATORY EXPERTS

Plaintiff recognizes that the Fourth Circuit has affirmed in both POP and sling cases Judge Goodwin's decision to exclude evidence relating to a manufacturer's compliance with the FDA's 510(k) process. In the event of a contrary ruling by a remand Court, Plaintiff reserves the

right to designate the following General Regulatory Expert(s):

1. Dr. Suzanne Parisian (Regulatory)
   MD Assist, Inc. 7117 N.
   3rd Street Phoenix, AZ 85020

2. Dr. Peggy Pence (Regulatory) Symbian Research International, Inc. 3537
   Old Conejo Road, Suite 115
   Newbury Park, CA 91320

II. Plaintiff's Non-Retained Expert Pursuant to Fed. R. Civ. P. 26(a)(2)(C):

Teri McNelis, MD, FACOG
2647 Cardinal Way
Buffalo, MN 55313

Dr. McNelis is an obstetrician-gynecologist board certified in obstetrics and gynecology with over 15 years of surgical experience. She is licensed in the state of Minnesota and is board certified in obstetrics and gynecology, and is a pelvic surgeon who has performed hundreds of procedures. Dr. McNelis was Plaintiff's treating physician, and is expected to testify as to her care and treatment of Plaintiff regarding the injuries alleged in Plaintiff's complaint.

Dr. McNelis may provide testimony and opinions consistent with her knowledge, experience, duties and responsibilities as a pelvic floor surgeon, her clinical experience, and review of literature. Such testimony may involve or require scientific, technical, or specialized knowledge that falls within the scope of F.R.E. 702, 703, or 705. In addition, any portion of Dr. McNelis's deposition testimony concerning these matters or the matters identified below may be designated by Plaintiff for use at trial, and such deposition testimony may likewise involve or require scientific, technical or specialized knowledge falling within the scope of F.R.E. 702, 703, or 705.

Dr. McNelis has reviewed literature on the Prolift and other devices to treat POP and SUI, and has treated adverse events in patients with mesh. She was trained by Ethicon preceptors on the Prolift and relied on the IFU as a source of her knowledge. As a result, Dr. McNelis is familiar with the procedural steps and warnings and adverse events in the Instructions for Use (IFUs) that would be associated with the Prolift device, and she is expected to testify that Prolift IFUs fails to warn of all the risks associated with Prolift mesh. Dr. McNelis may testify regarding the safety information that was not disclosed by Ethicon regarding their mesh and the long-term safety risks of the Prolift mesh meant to be permanently implanted in women's bodies, including the frequency and severity of those adverse events. She may testify that Ethicon never warned of the nature and severity of mesh shrinkage and contraction, degradation and other complications unique to transvaginal mesh. She may testify as the complexity and impossibility in removing the entirety of mesh in patients and the inappropriate and misleading language in the Prolift IFU.

Dr. McNelis will testify from a medical perspective regarding the risks listed in the Instructions for Use (IFU), and she may opine that the Prolift IFU was not appropriately written as to the sections for warnings, adverse reactions, and actions, and failed to disclose all risks associated with Prolift mesh. Dr. McNelis may provide testimony regarding the adequacy of the warnings, the adverse reactions, and actions sections in the Prolift IFU. She will also testify as to the specific warnings, adverse reactions, and actions that were or were not provided. Further, Dr. McNelis will testify that the IFU is intended to identify the specific adverse reactions that may occur from the Prolift device, and may opine that the Prolift IFU did not do so

Dr. McNelis is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. McNelis will offer testimony

and opinions about the design of the Ethicon device used in the plaintiff and how it specifically caused the complications suffered by plaintiff. The cause of the complications include the tissue reaction, mesh banding, mesh deformation, mesh contraction, mesh erosion, urinary retention, excessive tension from mesh contraction, and lack of compliance of mesh in-vivo.

Dr. McNelis will provide testimony regarding Plaintiff's urologic, pelvic or gynecological medical conditions, and those medical conditions that affect her urologic, pelvic or gynecological conditions. Included in this testimony will be the types, degrees, and causes of Plaintiff's incontinence and pelvic organ prolapse, as well as the injuries attributed to her Prolift mesh, including her relevant medical history and the medical conditions and symptoms she experienced both before and after she was implanted with Ethicon mesh. Dr. McNelis will testify that Plaintiff experienced pain during sex, pelvic pain, mesh contraction, and mesh contraction requiring surgical revision of the Prolift. The pain she experienced is a result of the Prolift mesh and design thereof. Dr. McNelis may provide testimony regarding the extent and duration of necessary medical treatment for any pelvic conditions experienced by Plaintiff while under her care.

Dr. McNelis may testify as to the life-long irreversible mesh complications including: punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, chronic irritation at the wound site and site of mesh, mesh roping and curling, mesh deformation and contraction, mesh stiffness and migration, permanent foreign body response, extrusion, erosion, exposure, fistula formation and/or chronic inflammation including mesh extrusion, exposure, or erosion into the vagina or other structures or organ, infections, temporary or permanent lower urinary tract obstruction, acute and/or chronic irreversible pain, voiding dysfunction, chronic pain with intercourse including pain to the patient and the patient's partner,

neuromuscular problems, including acute and/or chronic pain in the groin, high, leg, pelvic and/or abdominal area may occur, recurrence and worsening of incontinence, hematomas, fistulas, multiple revision surgeries that many never alleviate the reported symptoms, inability to safely remove the entirety of the mesh, urge incontinence, urinary frequency, urinary retention, and adhesions.

As a practicing surgeon for pelvic floor defects including pelvic organ prolapse, Dr. McNelis personally determined that the risks of Prolift far outweigh the benefits and discontinued her use of the product. In reaching this determination, she relied upon her clinical experience, the presentation of patients with mesh complications and her review of the applicable literature. More specifically, she will testify that pelvic organ prolapse is a prevalent condition that can affect a woman's quality of life. The other surgical procedures available to treat POP do not carry the same risk profile that transvaginally placed Prolift mesh does. Once she became fully aware of the true safety profile of the Prolift, she discontinued her use of the product.

Dr. McNelis may also provide testimony based upon her review of any document produced in the above-captioned matter, or offered as an exhibit, including documents that may not have been disclosed and/or produced to date. Further, Dr. McNelis may use the transcript of any hearing, deposition, or trial taken in the above-captioned matter. As such, Dr. McNelis may offer opinions with regard to several topics, including liability, specific causation, and the nature and extent of Plaintiff's damages.

Plaintiff reserves the right to supplement this expert disclosure upon discovery of additional information regarding the care and treatment of Plaintiff Naomi Larson.

Dated: October 8, 2019

Respectfully submitted,

/s/ Andrew N. Faes
Thomas P. Cartmell MO #45366
Jeffrey M. Kuntz MO #52371
Andrew N. Faes MO #59721
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Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2019, I electronically served the foregoing document via E-mail upon counsel of record in the above-captioned case.

/s/ Andrew N. Faes
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Counsel for Plaintiffs

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02326** **MDL No. 2326**
THIS DOCUMENT RELATES TO: ***Naomi Larson, et al. v Ethicon, Inc., et al.*** **Case No. 2:14-cv-22872**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT OPINION OF STACEY WALLACH, M.D.

All of the opinions that I offer in this Report I hold to a reasonable degree of medical or scientific certainty. I have based this opinion on my review of all case related material provided to me.

I. QUALIFICATIONS

I am board certified in Obstetrics and Gynecology and have a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery. I have been at the University of California, Davis in Sacramento, California since 2002. I finished my three-year fellowship in urogynecology/female pelvic medicine and reconstructive surgery at Long Beach (CA) Memorial Medical Center. I am a Professor of Obstetrics and Gynecology, subspecializing in Urogynecology at UC Davis. I have been Director of Urogynecology and Pelvic Reconstructive Services at UC Davis since 2003. I am an oral examiner for the American Board of Obstetrics and Gynecology. I am a member of American College of Obstetrics and Gynecology, Association of Professors of Gynecology and Obstetrics, American Urogynecologic Society, Society of Gynecologic Surgeons, International Urogynecological Association and the International Continence Society. I have been a reviewer for the American Journal of Obstetrics and Gynecology since 2005.

I do not have any proctoring or consulting relationships with industry. However, throughout my career I have met with industry representatives and given my opinion regarding their products, including representatives from Ethicon, American Medical Systems (AMS), Bard, Boston Scientific and Coloplast.

I consulted for AMS approximately 7 years ago at a one day meeting in Minnesota. The purpose of this meeting was to gather surgeon feedback on different meshes they had in development.

I am an academic physician practicing in a department with residents. I teach both the residents and medical students. I am involved in creating the surgical curriculum for our residents, including developing many of the anatomy skills sessions. I was also involved in creating the urologic and gynecologic part of an anatomy curriculum for a fourth year medical student elective in our medical school's anatomy lab. Our anatomy workshops incorporate understanding the interactions of the structures of the pelvis – the viscera, nerves, vessels, muscles, ligaments and bony pelvis - with the rest of the body including the abdomen, spine and lower limbs.

To this end, I have solicited unrestricted educational grants to put on surgical skills workshops for our residents. Ethicon sponsored one in 2003 on the TVT device. AMS also sponsored one in 2010, which was a cadaver workshop involving different types of slings – retropubic, transobturator and single incision. I also accept DVDs from medical device companies to review with my residents. Our past residents received a copy of the Bard pelvic anatomy DVD and were told by me about its inaccuracies, specifically the arcus tendineus fasciae pelvis and arcus tendineus levator ani being mislabeled. I also communicated this mistake back to Bard after I watched the DVD. More recently, our residents have been referred to the Boston Scientific Pelvic Floor Institute websight to watch educational videos about anatomy, prolapse and incontinence procedures.

Since I am at a tertiary care academic medical center, I am referred the more complex medical cases from our region. The catchment basin is north to Oregon, south to Bakersfield, west to San Francisco and east to Reno. Thus, I tend to see mesh complications after the surgeon has tried to treat the issue, sometimes multiple times, and often surgically.

At about the time trocar based pelvic organ prolapse mesh kits began to be marketed more and more by medical device companies, I was already skeptical about trocar based systems for prolapse use, since I had already seen patients with complications from Tyco's IVS Tunneller, which was the first system to pass trocars thru the ischiorectal fossa for support of the vaginal apex. However, because trocar based mesh kits were becoming more popular, I went to train on Bard Avaulta, AMS Elevate and Boston Scientific Pinnacle kits so that I was aware of what was being taught to our community doctors and could better understand patient problems after these procedures.

Starting in mid-2006 I began to see more patients with issues from trocar systems. I have removed Mentor's Obtape mesh, Tyco's IVS Tunneller mesh, AMS's Sparc, AMS's Apogee/Perigee, Ethicon's Prolift, Ethicon's Gynemesh, Coloplast's Restorelle mesh, Bard's Uretex sling, Bard's Marlex mesh, Boston Scientific's Pinnacle and Uphold, Bard's Pelvitex, Ethicon's TVT and TVT-O, AMS's Monarc and MiniArc, Bard's Avaulta Solo and Avaulta Plus, and Mpathy mesh, to name but a few. Having done this, I know that these procedures are complicated and a last resort to alleviate patient symptoms.

I have personally used Ethicon products including Gynemesh placed abdominally for sacral colpopexy and hand sewn transvaginally as well as Ethicon's TVT and TVT Exact midurethral

sling. I have also personally removed Ethicon meshes from both patients that I placed as well as placed by other physicians as mentioned above. I have not only seen the intraoperative changes but have also reviewed the findings of these products on a histologic level with our pathologists.

I have reviewed numerous Instructions for Use (IFU) for a variety of medical products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the devices.

I have extensive clinical experience with IFUs and instructing patients about the adverse events and risks contained in IFUs. I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs and consenting patients regarding IFUs.

I have significant experience with pelvic repair surgery.

I have personally examined, diagnosed and treated well over a hundred patients with mesh complications. I have personally observed and treated patients who have experienced the following device-related complications:

1. Chronic pelvic pain
2. Chronic inflammation of the tissue surrounding the mesh
3. Excessive scar formation, scar banding and contracture or mesh arms resulting in asymmetrical pulling/folding on the central portion causing pain
4. Pudendal neuralgia
5. Pelvic floor muscle spasms
6. Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging
7. Dyspareunia
8. Stress and urge urinary incontinence
9. Urinary retention
10. Constipation and fecal incontinence
11. Deformed, wrinkled, folded, curled, roped and fragmented mesh upon removal
12. Encapsulation of mesh
13. Vaginal shortening, tightening, stenosis and other deformation
14. Infection of the mesh itself
15. Development of persistent sinus drainage tracts
16. Infection as a result of the mesh including bladder infections, pelvic infections and vaginal infections
17. Vaginal erosion and extrusion
18. Mesh in the urethral lumen, bladder lumen and rectal lumen
19. Urethrovaginal, vesicovaginal and rectovaginal fistulas

I am familiar with Ethicon's Prolift kit specifically, as opposed to just mesh products in general. I regularly keep demo products from medical device companies including the IFU to review with residents to help them understand how these kits are placed. As such, I had a complete Prolift Total kit in my office including the IFU given to me by my previous Ethicon representative.

II. BASIS OF MY OPINION

In formulating my opinions and preparing this report, I reviewed Ethicon's Prolift IFU, the pertinent medical records pertaining to the care of Naomi Larson and Dr. Teri McNelis' deposition. The case specific material that I reviewed and relied upon to formulate my opinion is attached in the appendix. Based on my education, training and my experience removing all types of transvaginal mesh in general and Prolift mesh in particular, I am intimately familiar with the injuries and problems associated with these products. I have personally treated patients who have been implanted with Ethicon's original mesh and their later light weight mesh version used to treat prolapse. I have personally removed Ethicon mesh from the vagina, urethra and retropubic space. When removing Ethicon mesh products several years after their implantation, intraoperatively I have observed scar encapsulation, narrowing and folding of mesh arms. On a microcscopic level, I have visualized specimens showing chronic inflammation with giant cell reaction around the mesh fibers.

All of the opinions I have are to a reasonable degree of medical certainty. I understand discovery is still on going in this case, including the collection of additional medical records and additional depositions. I reserve my right to amend my opinion and provide additional opinions if and when further information and testimony becomes available. I also reserve my right to perform an independent medical exam prior to trial. Below are my opinions pertaining to Ms. Larson's care, her treatment and surgery, as well as her prognosis.

III. SUMMARY OF MEDICAL TREATMENT OF NAOMI LARSON

At the time of implantation of Ethicon's total Prolift implant on August 11, 2008 Naomi Jean Larson (DOB [redacted]) was a 33-year-old G5P8 s/p TAH in 2005 who was referred to Dr. Teri D. McNelis for chronic pelvic pain, dyspareunia, stress incontinence, grade 2 cystocele and grade 2 rectocele.

Ms. Larson's medical history was significant for prior pelvic surgery, depressive disorder, smoking, endometriosis, migraine, acute blood loss anemia, dyspareunia, cystocele, rectocele, insomnia, obesity, prior hysterectomy, pelvic adhesive disease, pelvic pain, and memory Loss.

Her surgical history included four cesarean sections, and abdominal hysterectomy 2005, hernia repair 2005, right oophorectomy 2002 for a cyst, laparotomy for a retained placenta after pregnancy, appendectomy 1984 at age 9, laparoscopy 2006 with lysis of adhesions.

Her social history was significant for being a homemaker raising 5 children. Ms. Larson was a former smoker who quit in 2006 with rare alcohol use and no illegal drug use.

Of note, I reviewed all of her medical records that were available at the time of creation of this report including records from before and after her implant surgery. Below are my notes from those records. I have not documented every encounter she had with the healthcare system, since she has had numerous but I have reviewed the records including but not limited to her records regarding her depression.

<u>6/1/2005</u>

Ms. Larson saw Dr. Michael McNelis, obgyn, for drainage from the right side of her cesarean section scar. Per the note, she underwent a repeat low transverse c-section on 5/25/2005 at Fairview Hospital. During the pregnancy she was a gestational diabetic. The delivery was difficult requiring use of both forceps and vacuum to deliver the baby during the c-section. On exam she was noted to have a 3-4 cm skin separation with drainage on the right side of the wound but no evidence of hernia or fascial dehiscence.

9/27/2005
Ms. Larson saw PA Hegg for pelvic pain that "feels like when had retained placenta" in the "center pelvis" which was very tender to palpation. She was admitted to Buffalo Hospital for a gynecologic evaluation where, at the age of 30, she underwent a total abdominal hysterectomy, excision of fatty epiploica of bowel and adhesiolysis performed by Dr. Thomas Minke. She presented with an acute exacerbation of her pain over four to five days with "very point-specific pain" in the setting of chronic pelvic pain with a history of endometriosis, significant scar tissue and adhesive disease. Intraoperatively she was found to have and incisional hernia with infarcted fatty epiploica.

12/7/2005
Appointment with PA Hegg for fatigue, light headedness and joint pain

3/15/2006
Visit with PA Hegg for depression, insomnia and obesity

6/1/2006
Visit with PA Hegg for nausea, headaches and anxiety

7/31/2006
Visit with PA Hegg for abdominal pain and pain with intercourse x 2 weeks that was sharp then constant pressure. The patient described the pain as similar to what she felt like when she had hernia surgery last year. She was referred to Dr. Michael McNelis for question of adhesions or endometriosis. A CT abdomen and pelvis was unremarkable.

8/1/2006
Ms. Larson underwent a diagnostic and operative laparoscopy with extensive lysis of omental adhesions performed by Dr. Michael McNelis due to two week history of severe lower abdominal pain. Intraop she was found to have "extensive omental adhesions below the umbilicus and extending inferiorly in the midline towards the pubic bone."

11/14/2006
Visit with Dr. Styrvoky for trouble sleeping

12/6/2006
Appointment with Dr. Styrvoky for follow up of her depression, Celexa working well x 5 years, increased somnolence and anxiety

5/14/2007

Visit with Dr. Styrvoky for epigastric pain with nausea after eating rule out gallstones

7/5/2007
Visit with Stella Ekong for medication management of her depression

10/1/2007
Consultation with Dr. Susan Hunt general surgery for tenderness along her c-section scar, no hernia felt. Plan was for CT scan and follow up with gynecology

10/4/2007
Visit with Dr. Styrvoky for 2 weeks of intermittent abdominal pain diffuse across lower abdomen without radiation with mild tenderness on exam. She was treated empirically for a urinary tract infection with cipro and consult general surgery.

10/10/2007
Call regarding depression and irritability for change in antidepressant

11/10/2007
Phone call sent to ER for severe epigastric pain

3/30/2008
Visit with PA Hegg for tension headache

7/15/2008
Appointment with Dr. Thomas Styrvoky for symptoms of stress urinary incontinence since April that were getting worse affecting her quality of life. She was referred to gyn "with special interest in urinary incontinence"

7/22/2008
Visit with Kari Hegg, PA where Ms. Larson describes her vaginal area as "swollen and there is some tissue bulging out. When she has sex, it is painful and it feels like it is hitting her bladder. She feels that she has to urinate frequently. Secondly, she has a hard time getting stool out of her rectum. She will often have to put her finger in her vaginal area and help push the stool out." She saw Dr. Styrvoky the prior week who did not perform a physical exam. On physical exam at this visit PA Hegg noted "extrusion of vaginal rugae, that is the excess tissue she is feeling. I also see the bladder prolapse down into the vagina with the Valsalva maneuver" and "a small rectocele". Her assessment was "cystocele with some stress urinary incontinence" and "rectocele" for which the patient was referred to urogynecology.

8/7/2008
Ms. Larson presented to Dr. Teri D. McNelis in consultation from Kari Hegg for stress incontinence. Per Dr. McNelis' notes "33 y/o G5P5005 who had a TAH in 2005 due to endometriosis. Since that time, she has had cramping daily, can't stand for long periods of time due to the pelvic discomfort, and dyspareunia. She would like to pursue treatment for this. She also leaks urine with coughing, sneezing, intercourse or any activity. She used to have urgency as well, but since she has started to fluid restrict herself, she has not had problems with nocturia,

frequency or urgency. For the last year, she has also been having problems with her vagina bulging out with bowel movements and activities. There is a small piece of tissue that bulges that particularly bothers her. She cannot empty her bowels well and actually has to splint to remove all of her stool. This problem is very troubling to her and she wants definitive management. A final issue is that she has deep dyspareunia ever since she had her abdominal hysterectomy. She did have a laparoscopy in 2006 and really had not improvement in her pain after that surgery. She would like someone else to try to fix this problem for her." On exam she had evidence of urethral hypermobility as well as a positive cough stress test with a small amount of leakage. The vaginal examination showed a "5mm x 1 cm area of redundant tissue in distal 1 cm of vagina on right. Grade II rectocele and cystocele with valsalva. Good apical support. Tenderness of upper anterior vagina with palpation."

Dr. McNelis' plan"1. Spent 30 minutes discussing treatment options. Recommended anterior and posterior colporrhaphy and sacrospinous ligament vaginal vault suspension to treat cystocele and rectocele. Also, will excise redundant piece of tissue that bothers the patient. Recommend repairing this with Prolift mesh to prevent further recurrences. Discussed risk of mesh erosion and need to use vaginal estrogens for the rest of her life. Discussed this may or may not relieve all of her symptoms.

2. Discussed that relieving her dyspareunia and pelvic pain issues is going to be extremely difficult. Once patients have developed pelvic adhesions, these are extremely difficult to eradicate. Offered her a laparoscopy with adhesiolysis and excision of endometriosis. Discussed placed Interceed, which is an adhesion barrier to prevent further adhesions from forming. Instructed that there are no guarantees that I will be able to alleviate her pain. She absolutely wants to retain her remaining ovary. Discussed increased risk of bowel and bladder injury due to adhesions.

3. Recommended proceeding with a TOT-sling for her stress incontinence issues. Discussed 80% success rate and small chance of post-operative urinary retention. Also discussed 1 % chance of making urinary urgency worse. She absolutely wants to proceed.

4. Reviewed risks of surgery including pain, bleeding, infection, damage to internal organs, risk of anesthesia, death and blood clots. Patient wants to proceed ASAP. Will do bowel prep."

8/11/2008
Progress note from Dr. McNelis copied from her 8/7/2008 encounter.

8/11/2008 to 8/15/2008
Admitted to Buffalo Hospital for surgery. Principal Diagnosis Causing Admission: Pelvic pain, cystocele, rectocele, dyspareunia and stress incontinence. Ms. Larson underwent a laparoscopy with lysis of adhesions, anterior and posterior colporrhaphy and sacrospinous ligament vaginal suspension via Prolift mesh, an Obtrex TOT-sling and cystoscopy by Dr. McNelis. There were no specimens. "On POD#1 she had a hbg of 6.3. She was symptomatic and given 2 units of PRBCs. Her hbg came back at 7.8. She was still symptomatic so she was given 2 more units of PRBCs. On the night of POD#1 the patient starting having increasing abdominal pain and right

shoulder pain. At CT scan was done at that time that showed a large ileus." By POD#4 she was still distended but passing gas and tolerating a regular diet prior to discharge home.

8/11/2008

Ms. Larson underwent a laparoscopy with lysis of adhesions, anterior and posterior colporrhaphy and sacrospinous ligament vaginal suspension via Prolift mesh, an Obtrex TOT-sling and cystoscopy by Dr. McNelis. She had an estimated blood loss of 800 mL. During the procedure Dr. McNelis entered into the abdominal cavity apically in the vagina which was closed in two layers. During the insertion of the Prolift mesh Dr. McNelis "I measured her anterior compartment, which was only about 5.5 cm. I then tailored the mesh to fit this compartment. I then put each arm of the mesh through each respective cannula and noted the mesh laid down nicely in the incision. I did tack the most anterior aspect of the mesh to the pubo-cervical fascia anteriorly. I then excised about 4 cm of the mesh posteriorly and tacked this down to the rectovaginal fascia with 2 interrupted sutures of 2-0 Vicryl as well. I then removed all of my cannulas and made sure that there was a lot of laxity with the mesh I then closed my vaginal incision with 2-0 Vicryl in running locking fashion. The patient was given 5 cc indigo carmine dye intravenously. I cut all the arms of the mesh close the vulvar incisions."

8/17/2008

Ms. Larson presented to the Emergency Department where she saw Dr. William Goodall for postoperative pain and vaginal bleeding after the "AP vaginal repair performed on August 11. Following that she had significant loss of blood and received 4 units of blood. She was discharged home 3 or 4 days ago and has managed well although after attending a social event yesterday she felt that she had increased vaginal bleeding and increased abdominal pain today." Examination revealed "suture lines on the anterior and posterior vaginal wall. There is a small amount of normal vaginal fluid with a pinkish-red tinge to it, but no active bleeding." Diagnoses included Postoperative pain, normal postoperative bleeding after vaginal surgery and urinary tract infection. Ms. Larson was prescribed Cipro 500 mg b.i.d. for 3 days. She was to "Contact OB/GYN tomorrow. Return if she has any further problems. The patient is stable and improved at the time of discharge."

8/18/2008

Ms. Larson called Dr. McNelis' office complaining of a lot of bleeding since surgery desiring to be seen. She was added to Dr. McNelis' schedule due to her chief complaint of post-op pain and bleeding. "She had spotting after surgery. When she went home, she has been a lot more active and has now been going through a pad every couple of hours. She is concerned something is terribly wrong. She feels a little weak but is otherwise OK." On exam by Dr. McNelis the incisions were healing well and the cuff was intact but she had "blood all over the perineum and did have about 20ccs of blood in the vaginal vault." Dr. McNelis thought she had "several areas that are oozing venous blood. We discussed that I had to make a large incision to take down her scar tissue, so she is more at risk of something like this happening. She could go home and take it easy or go to the OR and have a vaginal packing placed." The patient elected to have the packing placed to decrease the bleeding.

8/18/2008

Ms. Larson underwent a placement of vaginal packing and Foley catheter by Dr. Teri McNelis due to vaginal bleeding. She was discharged the next day on 8/19/08. Per the operative note describing her prior 8/11/2008 surgery "She did lose quite a bit of blood during that surgery and wound up having 4 units packed red blood cells after surgery."

8/24/2008 to 8/29/2008

Ms. Larson was admitted to Buffalo Hospital under Kari Hegg, PA with a principal diagnosis of pelvic abscess. On admission she had a two day history of fever up to 102, chills, sweats, worsening pain with movement, nausea, malodorous vaginal discharge, tenderness at the vaginal apex at the incision line and CT imaging "noted to have a 6 x 6 cm abscess at the top of her vaginal cuff. She had a vaginal reconstructive surgery on 8/8/08. She was placed on IV ampicillin, gentamycin and clindamycin." Her ultrasound was repeated which "showed no sign of a fluid collection or abscess." She was discharge home on a course of Levaquin and flagyl for an additional 2 weeks.

9/17/2008

Ms. Larson placed a telephone call to Allina Health Clinic. "Pt calling. Surgery 08/11/08 and 08/18/08. States she is now having cramping and is not feeling well since Sunday. Finished abx Friday. Denies temp. Is having drainage that goes between pink and brown. Told pt. that if she wants to be seen today, she should go to ER. Call routed to Dr. T. McNelis as pt. wants to talk to her before she does anything." Dr. McNelis responded, "I told her to come in tomorrow at 8AM. If my LPN is not here yet, I will room her myself. Thanks, TDM"

9/18/2008

Ms. Larson presented to Dr. Teri McNelis with the symptoms of vaginal mesh erosion and dyspareunia. She is "here today because she is having increasing pink and brown discharge. She thinks she can feel some exposed mesh vaginally. She and her husband tried having sex earlier this week and was unable to due to pain. She denies fevers, chills or foul vaginal odor. She has not been using her vaginal estrogens." On pelvic exam the " Posterior vagina is healing well and shows no evidence of prolapse or abnormalities. She has a 5mm by 3cm area of mesh erosion on the anterior vaginal wall about 4cm from the introitus. She also has some tenderness to the right of this where she has developed a small stricture of the vaginal. Above the stricture, she is non-tender, and I cannot feel any mesh erosion apically." Dr. McNelis "1. Discussed that this erosion may have occurred because she is not taking her vaginal estrogens. She needs to start using Premarin cream 1 gm per vagina q hs. 2. I don't think the stricture will be corrected without surgical intervention. I recommend that we take her back to the OR to remove some of the mesh in the right upper vagina and the anterior vagina to try to relieve the stricture. This is the same area that she previously had a stricture before we even did surgery."

9/18/2008

Message from Dr. McNelis "Please schedule her for a vaginoplasty and vaginal mesh excision due to a vaginal mesh erosion, stricture and dyspareunia to follow my first case on 9/22/08." Lab- RBC result - Still some mild anemia. She should take an iron pill 1 daily for one month.

9/22/2008

Dr. McNelis performed the first vaginal mesh revision surgery "vaginoplasty with excision of vaginal mesh" that had eroded on the right side of the vagina. Findings included "a 1-cm x 3-mm area of mesh that eroded in the anterior vaginal wall about 4 cm from the introitus. She also had an adhesion in her right vaginal cuff area. I actually noted about a 1.5 x 1.5 area of mesh that had eroded through this area as well." No specimens.

10/8/2008
Ms. Larson presented to Dr. Teri McNelis for follow-up regarding "excision of vaginal mesh on 9/22/08 due to vaginal mesh erosion, vaginal stricture. She has been using her Premarin cream daily. She and her husband did try to have sex and she said it felt like he was "hitting" something, and it hurt her. She is not having any vaginal odor or abnormal discharge." On pelvic examination the incisions appeared to be healing well. "No further mesh palpated. Some tenderness around area of right apical vaginal incision with some induration in this area." Dr. McNelis recommended refraining from sexual relations for 6 weeks, starting vaginal dilators "to help soften scar tissue at the right apex of the vagina, starting in 2 weeks. … insertion of dilator for 15 minutes in 2 weeks. Follow up in 1 month to see how she is doing."

11/5/2008
Ms. Larson placed a telephone call to Allina Health Clinic for an appointment with Dr. McNelis due to some problems and concerns she had regarding the surgery she had about 3 months prior.

11/10/2008
Ms. Larson presented to Dr. Teri McNelis for dyspareunia 14 weeks after the Prolift procedure and 7 weeks after her first mesh revision surgery "to remove some mesh due to dyspareunia…she continues to experience dyspareunia. She has tried to use dilators without success. There is an area in her upper right vagina that hurts her during intercourse and with the use of her dilators. She has been using her Premarin cream faithfully." On pelvic exam there was "No evidence of prolapse with valsalva. No evidence of mesh erosion on visual or manual inspection. I was able to place a pederson speculum in the vagina without difficulty. Tenderness to palpation of the right upper vagina. Small 2x2cm band of tissue that is palpable and very tender to the patient. No adnexal masses noted." Dr. McNelis "Discussed that I may or may not be able to diminish this band of tissue with yet another surgery. I offered her a continued trial with the dilators or physical therapy, both of which may help over time. The patient feels she cannot tolerate the dilators due to pain and wants to try a surgical intervention. Recommended making a vaginal incision over the area of the scar tissue and leaving then placing a Repliform graft (cadaver fascia) in this area. Discussed she will need to start the dilators within a couple days of her next surgery to prevent surgery adhesions from forming. I reviewed the nature of the procedure as well as the risks involved. We discussed the risk of pain, bleeding, infection, damage to internal organs and risk of deep venous thrombosis."

11/17/2008
Ms. Larson underwent her second mesh revision surgery "Vaginoplasty with excision of Prolene mesh with insertion of Repliform graft." Preoperative and post-operative diagnoses were dyspareunia and vaginal adhesion. No complication and no specimens. Indications included "pain with intercourse. I had felt a band in the right and left vagina that was painful to the patient in clinic." Intraoperative findings included the adhesion band "tighter on the left…some

redundant vaginal mucosa in the posterior vagina and then in the right vaginal fornix. Her vaginal length is approximately 8 cm and totally normal."

During the procedure Dr. McNelis, "used my scalpel to make about a 3.5-cm incision over the area of the left adhesion band and the left vaginal fornix. As I cut down to this adhesion band, I realized that I was cutting through some previous mesh. I then excised about 3 cm of Prolene mesh, and this did relieve the adhesion band that was encompassing her right and her left upper vagina. Unfortunately, there was a pretty large defect now that this mesh was removed. I did to try to obtain hemostasis with numerous interrupted sutures of 3-0 Vicryl and, unfortunately, I was having extreme difficulty getting hemostasis. I then obtained Gelfoam, soaked it in thrombin, and placed it in the defect to affect hemostasis. I then obtained Repliform mesh which had been soaking for over an hour in saline. I then cut out about a 3-x 3-cm area of the Repliform mesh, and placed it in the defect. I then tacked it down over the area of the defect in the left vaginal apex with 2-0 Vicryl in an interrupted fashion. About 6 sutures of 2-0 Vicryl were placed to keep the Repliform mesh stable. I then again examined her right upper vagina. At this time, I could no longer feel the adhesion band now that the pressure on the left had been taken off. I did have to place a couple interrupted sutures in the posterior vagina, where I removed the small nodule. I then double checked and made sure I could insert 3 fingers all the way to the apex of the vagina without any tension of the tissues. I then packed the vagina with a 2-inch gauze soaked in A&D ointment and left the catheter in place."

11/18/2008
Appointment with PA Hegg to have 3 moles on her face and one on her abdomen removed

1/7/2009
Visit with Dr. Styrvoky to evaluate a year history of arthralgias which gets worse throughout the day

1/19/2009
Ms. Larson presented to Dr. Teri McNelis for a 2 month follow-up after her 11/17/2008 revision surgery. Per the office visit notes, she is a "33 yo G5P5 who first had surgery for pelvic organ prolapse in 8/08. She has subsequently gone back to surgery now on 2 occasions for vaginal mesh removal due to mesh erosion and dyspareunia. She stated that she used a vaginal dilator for 4 weeks after her most recent surgery and was doing pretty well for pain control. She took 4 days off because she was going out of town. Once she started using the dilator again, she had more pain. She continues to have pain with deep penetration. She can have sex now, but it is painful. She denies vaginal bleeding.

She thinks she is leaking urine occasionally. She denies increased leak with cough or sneeze. The incontinence is spontaneous. She also has a lot of vaginal discharge. She has had to splint to have a bowel movement on one occasion as well. Denies any fecal incontinence. She does have hemorrhoids which make it hard for her to get completely clean. She is wondering if I could fix these as well. She states that her depression and anxiety issues are stable."

On physical exam there was no evidence of "recurrent urethrocele, cystocele, rectocele or vaginal vault prolapse. No leak with cough. Tenderness over the posterior vagina extending from

the right sacrospinous ligament to the left sacrospinous ligament. Very tender over mesh that is palpable in the right upper vagina."

Dr. McNelis "Discussed that due to the amount of pain she has on exam, I think we need to try to take her back to surgery and try to excise more of this mesh. I apologized profusely for this inconvenience. Risks/benefits/alternatives of the procedure were reviewed with the patient. Risks included but not limited to pain, bleeding, need for blood transfusion, infection, DVT, damage to other organs such as bowel, ureter, and bladder, and risks of anesthesia were reviewed with the patient. Patient desires to proceed." They also discussed the potential need to place a biologic graft "if I remove the mesh and she has a large defect present." Dr. McNelis also recommended urodynamic testing to evaluate her urinary incontinence but the patient preferred to hold off.

1/21/2009
Ms. Larson placed a telephone call to Allina Health Clinic. She was scheduled for surgery on 2/2/09 at 0900.

2/2/2009
Ms. Larson undergoes her third vaginal mesh revision surgery with Dr. Teri McNelis for "Vaginoplasty with excision of previous Prolift mesh and replacement with repliform mesh over the defect." Pre and post-operative diagnoses were dyspareunia. The findings included "4cm band palpable across the upper third of the vagina." The tissue removed of "mesh and torn vagina" was disposed of in the garbage. Under indications Dr. McNelis notes "she has continued to have painful intercourse since this procedure. I have taken her now to the operating room on a couple of occasions to remove pieces of the mesh. At her last examination in clinic the decision was made to try to remove all the posterior mesh in the vagina, because it seems to be causing her the continued pain." In the description of the procedure Dr. McNelis dictates "On examination under anesthesia, there was about a 4-cm band of the mesh that was causing some stricture in the upper vagina…. dissect the vagina off the superior and inferior aspects of the mesh, and slowly and meticulously removed all the palpable mesh in the posterior compartment. There was no rectovaginal defects noted after removal of the mesh, and there was no palpable defects. I then changed my gloves. Unfortunately, after removing the mesh, there was a gaping in the posterior vagina, about 4 cm, at the apex, reduced down to just about a centimeter at the introitus. I then obtained some Repliform fascia. We soaked this in normal saline for the assigned time. I attached the Repliform to the upper vagina with interrupted sutures of 2-0 Vicryl. I also sewed the Repliform mesh to the rectovaginal fascia near where it touches the perineal body. I then fashioned the Repliform mesh to fill the defect and secure this into position with 2-0 Vicryl around the entire vaginal defect. I then packed the vagina with 2-inche gauze. The gauze had A & D ointment applied."

2/9/2009
Ms. Larson saw Dr. Teri McNelis for a post-op appointment with "bleeding and large clots". Per Dr. McNelis' notes, the patient had "removal of vaginal Prolene mesh on 2/2/09. She had been feeling fine, but she painted all day on Saturday. That evening she started having more vaginal bleeding. Since that time, she has passed about 10 small clots. She has also been having increasing rectal pain. She has been having some nausea. She had "sweats" last evening and had a temperature of 100.8. She is still eating. She denies dysuria, urgency, frequency. No cough or

URI symptoms." A "Limited speculum exam revealed no clots or blood pooling in the vagina. No purulent vaginal discharge. Repliform mesh appears intact. Bimanual exam reveals tender mass (6 x 2cm) in the right rectovaginal fossa consistent with a hematoma. Rectal exam confirms exam." Dr. McNelis' encounter diagnosis was hematoma complicating a procedure and pelvic pain. They "Discussed that all of her activity must have caused some bleeding resulting in a hematoma. Discussed that she needs to be on broad spectrum antibiotics to prevent this from getting infected." She was treated as an outpatient with Rocephin 250mg 1M and Doxycycline 100mg po bid x 14 days. They discussed postoperative restrictions including "no excessive activity", repeat labs and follow up in 2 weeks or sooner as needed.

2/10/2009
Telephone message and letter to Ms. Larson stated no sign of bladder infection.

2/12/2009
Ms. Larson placed a telephone call to Allina Health Clinic "stating that she is having more pain now than she was on Monday and would like to have something for the pain. She is currently taking Percocet but states that this is not helping with the pain. She would like something stronger for pain. Pt states that she does not have a fever, but she does not have a thermometer to take it either. She states that the bleeding has slowed down since Monday. Spoke with Dr. Akram and pt. can have Oxycodone in addition to the Percocet. Pt will have her husband pick up RX at front desk. She will call if pain gets worse and will have her come in today to be seen by Dr. Akram."

3/2/2009
Ms. Larson presented to Dr. Teri McNelis for a 4 week post-op visit after her "removal of vaginal mesh with placement of cadaveric fascia on 2/2/09. She had a vaginal hematoma 2 weeks ago. She was on doxycycline bid for 2 weeks. She was feeling good and having no pain, so thought it was fine to try to have intercourse last night. She had pain deep on the left like she has had in the past and had "a lot" of blood. She is bleeding minimally now and having some cramping." On pelvic examination Dr. McNelis noted "All vaginal incisions are intact by visual and manual inspection. No further evidence of hematoma. No disruption of any suture lines. Appropriately tender over incisions. Some mild induration of the cadaveric fascia noted." She was reassured that her incisions were doing well, healing takes time and she should reframe from intercourse for at least 2 more weeks. "RTC in 2 weeks for final check. If all looks well, she can resume relations at that time."

4/16/2009
Visit with PA Hegg for progressive fatigue, depression where she describes the need to sit down to unload the dryer. She is referred for a rheumatology consult and sleep consult.

5/6/2009
Ms. Larson presented to the Emergency Department where she saw Tracy Powell for "two weeks of intermittent pelvic pain in the suprapubic region going to the left lower quadrant. It has been more painful to have intercourse last two weeks. Tonight, at about 6 o clock the pain came on again and it is not bleeding and is actually gotten worse. It hurts to stand or walk. She has had a hysterectomy with a right oophorectomy. She also had a cadaver graft in her vaginal wall. The

last surgery she had was in February. She has had no vaginal discharge or bleeding. She is having no trouble voiding and her stools have been normal. She took Motrin at about 4 o clock, but the pain came on he got worse at 6. She has not had intercourse for a couple of days. She has had some nausea but no vomiting. She rates the pain as a 7 and it's an aching cramping type of pain. No radiation of the pain into her back. Upper abdomen seems to be fine. No respiratory symptoms. She has not had a skin rash. No other associated signs or symptoms." A pelvic ultrasound was performed and Dr. Buss was consulted who scheduled for laparotomy for rule out ovarian torsion. On pelvic exam he noted "moderate to severe focal tenderness with fullness above vaginal apex on the left."

5/7/2009
Ms. Larson underwent an exploratory laparotomy for possible left ovarian torsion by Dr. James Buss. Dr. Buss performed a left salpingo-oophorectomy for a pre and postop diagnosis of acute LLQ abdominal/pelvic pain, ovarian etiology. Intraoperatively, no torsion was found. The operative report describes "The left ovary was mildly cystically enlarged and adherent to the vagina and left pelvis and did appear to be the source of the pain."

5/22/2009
Ms. Larson presented to Dr. Teri McNelis for a 2 week post-op visit after an x-lap/LSO performed by Dr. Buss. "She is doing well. She is ambulating, eating, voiding, passing flatus and having bowel movements without difficulty. Her pain is minimal. She denies any significant wound drainage. We reviewed the results of the surgery and the final pathology." She was told to resume her normal activities and return to clinic for a follow up in one month.

6/17/2009
Emergency room visit to Buffalo Hospital for depression, started crying at work after she found out they were 3 staff short for the nursing home.

6/26/2009
Dr. Thomas Styrvoky prescribed her cipro and flagyl for a one month history of stomach pain and diarrhea

6/29/2009
Ms. Larson placed a telephone call to Allina Health Clinic wanting to increase her dose of Estradiol due to "moody" and having a lot of hot flashes. Dr. Teri D McNelis doubled the estradiol dose.

9/13/2009
Emergency room visit to Buffalo Hospital for a 10 day history of midline and suprapubic abdominal pain "similar to when she has had a bladder infection in the past." She was treated with Septra and pyridium for a urinary tract infection

11/15/2009
Visit with PA Hegg for strep throat

7/14/2010

Dr. Teri McNelis wrote to Ms. Larson. "We have been trying to reach you by phone and have been unsuccessful. A refill has been done for your Estrace. This is a medicine that you will have to take until around the age of 50. Either Dr. Strovoky or Kari Hegg should fill from here on out or you should see me for further refills if having problems. Every few years you should see if you can go down to 2 or 3mg of estradiol rather than the 4mg that you are needing now."

7/24/2010
Telephone encounter with Dr. Teri McNelis. "Patient is in surgical menopause and will need to be on HRT until age 50. Refilled meds for the next 6 months. Either Dr. Styrvoky or Kari Hegg should fill from here on out or she should see me for further refills if she is having problems. Every few years she should see if she can go down to 2 or 3mg of estradiol rather than the 4mg she is needing now"

8/31/2010
Appt with Dr. Lucas Hintermeister to establish care. She was having fatigue and depression. Rheumatology diagnosed her with fibromyalgia. She also complained of migraines and weight gain since her prolapse surgery.

11/15/2010
Visit with Robert Bendickson, PA for viral upper respiratory illness and viral pharyngitis

7/28/2011
Appt with Andrea Schult, PA for pain control related to fibromyalgia

8/8/2011
Visit with Dr. Robyn Casey for shoulder pain

9/19/2011
Appointment with Dr. Graham for lip lesion which could be a cold sore, referred to Dr. Pappas

9/20/2011
Visit with Dr. Gail M. Lundeen for difficulty with defecation, rectal incontinence, hemorrhoids and urinary incontinence. On exam no prolapse, urinary or rectal incontinence was seen. The assessment and plan notes "I suspect the minor urinary incontinence she is noting is from retention of urine within the urethra due to slight overcorrection of the urethrovesical junction angle". The notes go on to say the rectal incontinence "is secondary to occasional loose stools without intervention as well as some disruption of nerve sensations having undergone multiple repetitive vaginal surgeries with mesh placement and mesh removal twice." She was referred for pelvic physical therapy.

10/4/2011
Visit with PA Schult for back pain with assessment of upper back muscle strain and neck strain

11/4/2011
Visit with Dr. Graham for insomnia

1/17/2012
Visit with Dr. Graham for leg pain after a fall

6/4/2012
Visit with Dr. Graham for lip cyst sent to plastic surgeon

6/20/2012
Visit with Dr. Paul Brunk for left flank and abdominal pain likely related to passage of left ureteral stone, “questionable left pelvic mass”. To follow up with Dr. Graham.

6/21/2012
Visit with Kathleeen Guetschoff for pain thought to be related to a kidney stone, recent ER visit 6/16/2012. Schedule urology appointment.

6/21/2012
Telephone call that she was seen in the ED, continues to have 6/10 pain. Appointment made with urologist for following day

6/22/2012
Ms. Larson presented to Dr. Chase Sovell for a urology consultation. “She was seen in the ER for "excruciating" pain and was sent home on antibiotics (Bactrim). She returned to the ER. This is associated with a weak stream and flank pain. She "just wants this to go away." It feels like a spasm that is nagging between times. Her pain is worse in her left lower quadrant and groin area. She does not have dysuria.” Her 6/16/2012 CT of Abdomen was reviewed and a cystoscopy performed. Per the plan, “Her work up thus far Is normal from a GUI point of view. I did review the CT images and there is a small fleck of calcium in the wall of the upper left ureter. I’ll obtain a renal scan to evaluate for obstruction. It is possible that she passed a small stone or had a UTI that is slowly resolving. She is tender to palpation of a spot over the lateral edge of the sacrum on the left side. This indicates some type of musculoskeletal pain as well.”

6/25/2012
Message to Dr. Graham about the ER visit and her CT scan. Dr. Graham reviewed the records, recommended doing the renal scan and thought she may have passed a stone. Dr Graham suggested if the renal scan was normal and the pain not resolved by the end of the week to repeat the CT scan.

8/17/2012
Visit with Dr. Graham for a rash on face and arms which developed after her children had rashes. Treated with steroid taper

8/27/2012
Visit with Dr. Graham for fever and follow up of rash x 2 weeks that was treated with a steroid taper. Notes describe “Some bladder pain but no burning with urination.” Labs were sent

2013
Multiple telephone calls during the year for med refill

7/8/2013
Routine eye exam with Sandra Connell, OD

7/18/2013
Visit with Kathleen S Guetschoff, NP for annual adult female exam. Declined pelvic.

2014
Multiple telephone calls during the year for med refill, pick up prescriptions

1/22/2014
Call to Dr. Graham about pain in the bladder area. Referred to urology

2/5/2014
Ms. Larson presented to Dr. Patricia Schuster for abdominal pain and pelvic pain. Per Dr. Schuster's note, the patient was looking for a physician who could help her "chronic pelvic pain that radiates to her back and has been present for 3 to 4 years. This apparently started some time ago after she had a urinary incontinence and a pelvic sling procedure." Per Dr. Schuster's notes her assessment was "Chronic pelvic pain, most likely related to multiple previous surgeries, possibly the pelvic sling. I informed the patient that I do not put these in and I also do not take them out. I have no experience with the pelvic slings, other than bad anecdotes that I have heard from patients. The patient is not in with complaints of rectal symptomatology. She really is looking for someone to deal with her urinary problems. She had seen Dr. Sovell and apparently was dissatisfied with his consultation. She is seeking a new provider. I did discuss this with Dr. Lundeen as I had no information on any referrals as to where to send her. Dr. Lundeen had given the information suggesting that a physician at Park Nicollet-- Dr Gerten-- has some expertise with the pelvic slings and so referral is placed for the patient to go there and I did contact managed care to assist in that referral. The patient will return here only on an as needed basis. I did offer her to send her to the incontinence clinic to see if any of the biofeedback would be helpful, but after discussion, she was going to wait for the referral."

2/24/2014
Ms. Larson presented to Dr. Kimberley A. Gerten, Urogynecology, for consultation due to pelvic pain at which time Dr. Gerten took a detailed history and performed a physical exam. Parts of Dr. Gerten's notes follow. The HPI noted a "38-year-old, para 5 female, seen in consultation regarding the development of pelvic pain. She notes the pelvic pain has been present for 3 to 4 years, but more constant over the past year, is located in the lower abdomen and pelvis and radiates to her back. This all started in the year 2008/2009, where she underwent consultation by Dr. Terry McNelis regarding the development of post hysterectomy pelvic organ prolapse. She underwent the following surgeries.
1. 08/11/2008: Diagnostic laparoscopy with lysis of adhesions, total Prolift, anterior and posterior colporrhaphy, TOT mid urethral sling.
2. 08/18/2008: Return to the operating room 1 week following primary surgery for repacking secondary to excessive bleeding.
3. 09/22/2008: Vaginoplasty performed with removal of exposed vaginal mesh due to pain and dyspareunia.

4. 11/17/2008: Repeat vaginoplasty in the operating room with excision of previously placed polypropylene mesh and placement of Repliform mesh.
5. 02/02/2005: Return to the operating room for additional vaginoplasty with placement of Repliform mesh.
She notes that the pain is located above the pubic bone and radiates laterally to the lower back. She does get some relief with lying down. She does have trouble sleeping, but notes that it is not related necessarily to her pain.

She was seen in the emergency department on 01/24/2014. She has undergone previous evaluation by a urologist, Dr. Sovell on 06/22/2012. Cystourethroscopy was performed at that time with normal findings. She was uncomfortable with that clinical encounter. Regarding her bladder function, she denies any urinary incontinence, voids 3 times per day, nocturia x1. No hematuria. Recent creatinine 0.7.

Bowel function is daily once to twice. No splinting. No fecal incontinence.

She underwent a CT scan of the abdomen and pelvis in 06/2012, where there was a noted kidney stone, nonobstructive.

Transvaginal ultrasound on 01/22/2014, showed no ovaries or uterus. No pelvic fluid.

Following her 5 procedures with Dr. McNelis in the year 2008 to 2009, she was good for about a year after that. Then, she started getting period-like cramping, continued to get worse. She was using narcotics for relief. It is so significant that she cannot stand up when it is bothering her. Narcotics are the only thing that have helped at this point. It is hard to stand and do activities, sitting, standing. She cannot run. It is like it is ripping out of her with running. Over the past couple of months, she has needed Percocet. It used to come and go, but now the pain is consistent. Sherry Graham is prescribing Percocet.

GYNECOLOGICAL HISTORY: She denies any vaginal bleeding. Has a history of dyspareunia. She takes estrogen by mouth, Estrace 2 mg daily. She is able to climax, is sexually active. Had 1 spontaneous vaginal delivery and 4 cesarean section deliveries."

On pelvic exam Dr. Gerten noted that "she has normal-appearing external genitalia with good sensation. Positive bilateral bulbocavernosus reflexes. Parting of the labia shows a good estrogenization, normal appearing meatus and introitus. Total vaginal length is 10 cm. Aa -3, Ap -3. No evidence of pelvic relaxation. Gentle 1 finger digital palpation shows some residual mesh bunching at the corner of the inferior ramus and the pubic bone bilaterally. The pain is located in this region, left greater than right. The bladder base and urethra itself are nontender to palpation. The levator musculature posteriorly and laterally are nontender to palpation. Normal anorectal tone with no rectal lesions."

Dr. Gerten's assessment was "vaginal and pelvic pain subsequent to extensive pelvic floor surgery". She goes on to describe point specific pain that she is associating with the location of the residual Prolift mesh "pinpoint tenderness at the junction of the inferior ramus…at each

corner anteriorly and laterally left greater than right. Most likely, this is secondary to scarring and residual pain".

They "discussed her pelvic floor findings using a mirror, diagrams, literature and pelvic model and discussed options for treatment." Dr. Gerten recommended pelvic floor physical therapy with myofascial tissue release and using a neuropathic pain agent instead of long-term narcotics.

6/22/2014
Email to Dr. Graham saying she does not have health insurance at the present moment, she started a new job and is trying "to prevent unnecessary visits by emailing you first."

7/11/2014
No show for appointment with Dr. Richard A. Blackburn

9/16/2014
Visit with Dr. Graham to recheck fatigue, medication management

2015
Multiple telephone calls during this year for med refill eg. Concerta

1/9/2015
Ms. Larson presented to Dr. Shari L. Graham for chronic fatigue and urinary incontinence. She "takes the Concerta in the morning … is able to function after taking this… Also having issues with incontinence. Has stress incontinence and at times has a sudden urge to go and can't get to the bathroom in time. She has had surgery and has chronic pain from the mesh. She does not want to pursue this further at this time. She will consider bladder control medication and let me know if she decides to try this." Plan includes consider ocybutinin.

7/3/2015
Naomi J Larson is a 40 y.0. female who presents for annual exam and medication refill
HPI: Naomi currently does not have insurance. She does however need immunity titers done for school. These are reviewed and a few were done in the past. She was not immune to rubeola or mumps so MMR was given. These will be rechecked today along with TB Gold test. Feels her medications are working well for the most part. Concerta helps her to stay awake. She does feel the afternoon dose is not that helpful and wonders if this dose could be increased. Currently taking 54 mg in the morning and 18 in the afternoon. Currently picking up her medications one week at a time and wonders if she could have this written for one week at a time. If she is given 30 pills the pharmacy will give her 7 and not keep the rest on file.

11/10/2015
Ms. Larson presented to Dr. Shari L. Graham for evaluation of depression and pelvic pain. Naomi continues to have issues with chronic pelvic pain. Feels this started after her sling surgery. She has had a complete hysterectomy and oophorectomy. Has had vaginal repair, cystocele repair and sling with mesh. Has had chronic issues since mesh surgery and sling surgery. Feels there could be an erosion from the sling. Does not have any burning with urination or frequency. Sometimes has bladder spasms and feels like she is having contractions

or period cramps. Has taken pain medication for this in the past doesn't want to take pain medication chronically and isn't able to take this at work. Would like referral to gynecology. She has seen Dr. Lundeen in the past and was told she would need a specialist. Make appointment with gynecology.

11/11/2015
Call to Dr. Graham for note that she is under Dr. care and takes Concerta

1/2/2016
Call for prescription refill. Notes difficulty taking time off of work for an appointment since started a new job.

2/16/2016
Visit with Dr. Graham for medication management.

6/10/2016
Visit with Dr. Graham for multiple complaints. "Has a lot of pain in her rectum. Has always had issues with the mesh that was placed during her rectocele repair. Has pain every time she has to have a bowel movement. This pain is severe and feels like spasms in her rectum. This can be very disturbing if it occurs in a store or at work. Pain is so severe she can't walk." Consult placed to colorectal surgeon.

6/16/2016
Telephone call regarding ED visit on Monday for abdominal pain, increased white count and watery stools.

6/22/2016
Colonoscopy

7/6/2016
Office visit with Dr. Michelle Haroldson regarding her sleep apnea with notes also from Dr. Graham.

7/8/2016
Appointment with Dr. Francis Abraham for cholelithiasis. "Ultrasound examination shows a solitary gallstone without any ductal dilation pericholecystic fluid or gallbladder wall thickening." Surgery scheduled for 7/13/2016.

7/15/2016
Follow up visit with Dr. Francis Abraham after her laparoscopic cholecystectomy

9/14/16
Ms. Larson presented to Dr. Shari L. Graham to discuss sleep study. "Continues to have chronic rectal pain and chronic pelvic pain. She was to see a rectal specialist for this, but they told her to see a gynecologist. She has seen gynecologist in the past and this was not helpful. Feels her pain

is secondary to previous vaginal surgery." Dr. Graham referred her to obgyn for her pelvic floor dysfunction, her chronic pelvic pain and her chronic rectal pain.

10/1/2016
Ms. Larson sent a message to Dr. Graham about having difficulty with her CPAP.

10/25/2016
Appointment with Dr. Graham for medication management

4/3/2017
Ms. Larson presented to Dr. Shari L. Graham. "Naomi is feeling well overall. Was recently admitted to Fairview and had ECT treatments. Seemed to work really well in the beginning until the treatments stopped. Effexor has now been increased to 375 mg daily. Feels this helps. There is the option of ECT maintenance therapy, but she does not want to do this because she would not be able to work. Had significant memory loss from the treatment. Was having issues with leaking for 6 months. Now having incontinence of urine for 1.5 months. Can't stop it once it starts coming out. Did have a bladder sling, mesh, vaginal repair and rectocele in 2009. Gynecology did this procedure. A few years ago, Dr. Lundeen said everything was in place. Having pain when she is about to have a bowel movement. Started about a year ago, but now happening more frequently. Does not happen with every bowel movement. Happens about 50% of the time. When it happens she has to go to the bathroom right away. 75% of the time she has diarrhea. When the pain is high (feels like labor pains), she is unable to move and becomes incontinent of bowel. Pain does not happen when her stool is formed. Has had her gallbladder removed. Still having trouble with sleep." Also having pain on the inside of the left ankle which comes when she is walking. She has nausea when she has a migraine and tachycardia which she thinks is due to caffeine. Labs ordered, meds refilled and needs appt with gyn.

5/4/2017
Refill request Estradiol

5/18/2017
No show consultation

6/9/2017
Labs- Fatigue and arthralgia.

6/12/2017
Positive ANA refer to Rheumatologist

6/13/2017
Refill request Estradiol

6/19/2017
Follow-up phone results R/T S&S with ANA results. Fatigue and nausea.

9/11/2017

Visit with Dr. Shari Lee Graham for abdominal pain and diarrhea and sleep problems. "Naomi hasn't been doing well. She is struggling with chronic fatigue. Yesterday she was only able to be up for 6 hours. She is having abdominal pain and diarrhea. She has been having up to 6-10 loose stools daily since about March. Hasn't had any stool studies done or anything since it started. No blood in stool that she has noticed. A year ago she has abdominal pain with blood in stool had a colonoscopy that was normal. She has been seeing a psychiatrist for chronic fatigue. She was started on Vyvanse recently and this isn't helping. Hasn't notified her psychiatrist yet. She is very frustrated. Did see rheumatology for elevated ANA. Rheumatologist started her on Plaquenil she thought it may have been causing some of her abdominal pain. She was taking Prednisone when she saw the rheumatologist so she wasn't having any symptoms at the time. Stopped the plaquenil about two weeks ago." Labs ordered for the diarrhea.

10/4/2017
Visit with Dr. Andrew Peltier. "Naomi J Larson is a 42 year old woman with history of fibromyalgia, mild obstructive sleep apnea, PLMD, migraines, irritable bowel syndrome, and positive ANA who presents to establish care.
• Somnolence, fatigue, mild obstructive sleep apnea on 6/2016 sleep study.
CPAP ordered in 7/2016 with Dr. Haroldson, but had to discontinue use due to poor tolerance.
She also stopped the Requip; takes clonazepam for the legs and sleep.
She was on Concerta in the past, changed recently to Vyvanse with psychiatry but stopped this.
Concerta was more effective but she would like a trial off stimulants.
• Positive ANA.
Reviewed consult with Dr. Hausch via CareEverywhere. He found no clinical signs of inflammatory arthritis. Started trial of hydroxychloroquine 2 months ago. She notes slight improvement in fatigue in the past week or so.
• Confusion, word finding difficulty.
Notes symptoms especially over the past week. Loses train of thought, cannot think of the word she wants, difficulty operating the elevator in clinic today.
She had ECT one year ago, had similar symptoms immediately after ECT.
Difficulty focusing at work." Recommended neuro consult, will discuss further sleep testing and mandibular advancement for her sleep apnea.

10/30/2017
Consult- Dr. Peltier. This patient had a severe depression last year. This required ECT treatment The patient has noted some memory difficulty since then. The patient feels that her depression is under control and does not feel that she has much anxiety with the depression. The patient has been working as an RN in the emergency room at one of the cities hospitals. The patient feels that she is struggling to remember things that she is being told and has to repeat medication dosing multiple times. The patient does carry a diagnosis of fibromyalgia. There is no family history of dementia at a young age

10/31/2017
MR Head Brain WO for confusion, visual changes and amnestic mild cognitive impairment.
Impression:
1. lntracrania! structures are normal without change.

2. Mucosal thickening and trace effusions in the right mastoid sinus are new. Considerations include inflammatory disease and
serous effusions

11/6/2017
Follow-up- fibromyalgia, recurrent major depressive disorder, chronic fatigue, prophylactic vaccination flu. Naomi J Larson is a very pleasant 42 year old woman here for follow up on recent establish care appointment with me as well as neurology consultation for episodes of confusion, word finding difficulty. Since her last visit she stopped working her extremely stressful job and is feeling much better. Her thought processes are back to baseline. She had normal brain MRI, ANTl-NEUTROPHIL CYTOPLASMIC ANTIBODIES, and Lyme with neuro. She does have an EEG pending. She called re: neuropsychological testing and first available is in Feb 2018. She took a new job as a hospice nurse and is looking forward to starting this job. She has had extremely severe depression requiring ECT and now on high doses of Effexor and Wellbutrin with close monitoring for serotonin syndrome with her psychiatrist. Dr. Andrew Peltier

11/8/2017
Labs results- negative for Lyme screen and ANCA

2/22/2018
Office visit cancelled

4/23/2018
Refill request - Estradiol

8/30/2018
Office visit cancelled

12/24/2018
Artificial menopause refill request, Estroadiol. Last office visit 11/6/17

3/18/2019
Called for another sleep study

3/21/2019
Sleep Problem; diagnosed with hypersomnolence, last sleep study 2016, mild apnea and restless leg syndrome. Did not tolerate CPAP and discontinued it. Also discontinued the Requip. Treating her restless legs with clonazepam. She is on high doses of Adderall per day. She continues to have severe daytime somnolence and is missing work as a result.

7/25/2019
Prescription for Estradiol 2 mg tab by Dr. Donald Peltier

IV. EXPERT OPINION

All of my opinions in this report I hold to a reasonable degree of medical certainty.

A. Ethicon failed to adequately warn physicians and patients about known problems with their Prolift product.

I am familiar with trocar based delivery systems for both slings and prolapse. I have performed retropubic, transobturator and single incision slings. For each new procedure that I learn I make it my practice to review the IFU as well as make the residents read and review it, and I try to keep a copy in a file.

In terms of mesh use for prolapse, I perform both vaginal approaches and abdominal approaches (abdominal sacral colpopexy). I initially used cadaveric fascia for my vaginal paravaginal repairs, then tried Pelvicol and Pelvisoft but was not happy with the poor healing over the graft. This information was communicated to my Bard representative. I then used either hand sewn mesh (Gynemesh) or human dermis (Alloderm/Repliform). Although I was trained on many companies' vaginal mesh kits, I did not start using a mesh kit for prolapse repair until September 2010, when I began using Boston Scientific Uphold, which is not a trocar based system. To date, I have performed 23 Uphold implant procedures. Conceptually, I was concerned about the passage of trocars through spaces that as gynecologists we do not usually encounter. I was also very familiar with the Capio device in Boston Scientific's kit since that is the same suturing instrument I had used for over 10 years for my hand sewn procedures. Lastly, I was satisfied with my results the way I was performing these surgeries and thus had not been convinced to change since the long term data showing benefit from trocar based polypropylene mesh prolapse kits was lacking and I was seeing complications with such meshes.

I used the Uphold device primarily in older less sexually active women, who had a uterus in place and desired or had medical indications for a shorter procedure. This procedure did add to my armamentarium for those patients who otherwise may have gotten a vaginal sacrospinous ligament suture fixation with the uterus in place (hysteropexy).

Being salaried in academic medicine, I did not have the same monetary driving factors that potentially other physicians faced to do more cases in less time in order to bring in more money.

The Instructions for Use booklet (IFU) is one medium that physicians reasonably rely upon to make informed decisions about whether and how to use a medical device. The contents of the IFU should assist the physician in his or her risk-benefit analysis that is employed when determining whether to recommend a particular product as a surgical option to a patient. I have read and am familiar with the IFU for the Prolift Pelvic Floor Repair System mesh kit. I have reviewed the IFU for many other medical products that I have implanted in patients in the 20 years that I have been practicing urogynecology. The IFU failed to warn physicians about the potential adverse events that may be associated with the product, including but not limited to the frequency, severity, duration and potential permanence of those adverse events. If a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to those using its products.

Under performance, the Prolift IFU states that animal studies show the "mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains *soft and pliable*, and normal wound healing is not noticeably impaired." Under warnings and precautions the Prolift IFU states "correct use of the device will minimize risks. Transient leg pain may occur and can usually be managed with mild analgesics." Under adverse reactions the IFU says "Potential adverse reactions are those typically associated with surgically implantable materials".

If a medical device manufacturer knows that the design features of its product cause or increase the risk of a complication, or present a risk unique to that product's design, then it is misleading and inadequate for that manufacturer to represent to users of the device that the risks associated with that product "are those typically associated with surgically implantable materials," especially when this can be construed to mean biologic grafts as well.

Based on my education, training, and experience in complicated pelvic floor reconstructive surgery, as well as my familiarity with published medical and scientific literature relating to mesh complications, I am aware that chronic inflammation, excessing scarring and banding leads to scar plating and shrinkage of the mesh which causes a host of problems when placed in the transobturator space. Transobturator mesh including the Prolift transobturator arms can roll or curl which damages tissue affecting mobility. The mesh can also cause tissue shrinkage with tissue ingrowth that happens during normal healing with scar formation, becoming tight from the scarification. In addition, as the body heals the scar or shrinkage does not occur symmetrically, causes chronic inflammation and pulling on the tissues where it is implanted.

If a medical device manufacturer knows that the design features of its product cause or increase the risk of a complication, or present a risk unique to that product's design, then it is misleading and inadequate for that manufacturer not to disclose this. Failure to provide physicians with relevant information bearing on the potential safety of a product that is known to the manufacturer prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to the implantation of the medical device in their body.

Ethicon failed to provide any warning about the frequency or extent of mesh shrinkage known to be associated with polypropylene mesh. To the contrary, Ethicon's Prolift IFU suggests their mesh construction of knitted filaments actually reduces this risk because it is "knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than the standard PROLENE mesh."

Ethicon did not warn doctors that the use of trocars inserted blindly presented an unnecessary risk of nerve and tissue trauma because these spaces are not void of structures. For example, the ischiorectal fossa contains nerves and blood vessels with anastomotic connections between the internal and external iliac system which can make bleeding harder to control.

The Prolift IFU fails to disclose the possibility of persistent vaginal bleeding, persistent granulation tissue, recurrent mesh erosions, scar banding, dyspareunia, ambulation difficulties

and chronic pain including but not limited to leg pain, groin pain, back pain and pelvic pain. The Prolift IFU fails to disclose the possibility of contracture of mesh arms resulting in asymmetrical pulling on the central portion, vaginal shortening, tightening, stenosis and other deformations.

Furthermore, the Prolift IFU fails to disclose the possibility of persistent voiding dysfunction including retention, dysuria and recurrent urinary tract infections, new onset or worsening of urinary incontinence symptoms including both urge and stress related. Nor does the IFU disclose the possibility of persistent defecatory dysfunction including fecal urgency, fecal incontinence, incomplete ability to evacuate and rectal intussusception.

Lastly and most importantly, the IFU fails to disclose the inability to remove the entire mesh. Ethicon knew that the permanent implantation of surgical mesh may make future surgical repair more challenging, that mesh implantation may put the patient at risk for requiring additional surgery for development of new complications, that removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life, and, that complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain. It is extremely difficult and almost impossible to remove the TVT Prolift mesh in its entirety once it is implanted. Even to remove portions of the product necessitates invasive surgery that few surgeons are qualified to perform. Ethicon failed to warn about these risks and failed to provide any instruction or direction as to how to address complications, or what to do in the event removal was necessary.

B. The design of the Prolift products is defective.

Unlike mesh placement for abdominal sacral colpopexy where the mesh is attached apically to the anterior sacral ligament causing the orientation of the forces in a vertical fashion parallel to the length of the vagina with contracture of the mesh occurring vertically, the design of the Prolift anchors laterally meaning any contracture of the mesh pulls at the pelvic side walls. As the four anterior mesh arms scar into tissue, they can pull asymmetrically on the central portion of the mesh. This results in the buckling, folding or wrinkling of the center mesh portion, which is intended to stay flat between the bladder and vagina and/or the rectum and the vagina. This, in turn, causes pain and can lead to erosion or extrusion of the mesh through the vaginal mucosa. The arms of the mesh pull on their anchoring points in the pelvic sidewall muscles (obturator and levator ani), tending to pull these anchoring points and the attached muscles toward the midline. This asymmetrical, non-uniform pulling on the pelvic sidewall muscles causes pain at rest, sitting, walking, during sexual intercourse, during defecation, and during normal daily activities like coughing and straining. Attempts at defecation or sexual penetration push on the mesh, aggravating the pulling on the arms, which in turn causes new or worsening pain. During many normal activities, pressure is placed on the mesh, which is transmitted to the attachments in the pelvic sidewall, also deforming and pulling on the muscle at the attachment points.

In the hands of many gynecological and urological surgeons, the blind passage of the metal trocars done during the implantation is unreasonably dangerous and presents the unnecessary risk of tissue damage, vascular damage, nerve damage, and internal trauma that can be greatly reduced if not eliminated with other, safer designs.

The pelvic floor needs to be supple and flexible to perform its many functions. It must accommodate movement and forces associated with activities of daily living, such as coughing, walking, exercising, bladder filling and emptying, defecating, and sexual relations. Polypropylene mesh placed transvaginally is stiffer and less flexible than the native tissues of the vagina, and scar plate formation and mesh stiffness are incompatible with the natural functioning of the vagina. Ethicon should have known from published literature and it experience with this mesh used for abdominal hernia repairs that the polypropylene mesh could become rigid and restrictive inconsistent with the requirement for the vagina of far greater flexibility than the abdomen.

It is virtually impossible to remove all of an armed transvaginal mesh implant, and it is extremely difficult and traumatic to the patient to attempt to remove portions of the Prolift mesh once it is implanted. The inability to remove all of the mesh can cause long-lasting complications, including chronic pain. Surgeries to attempt to remove pieces of the mesh increase the presence of scar tissue, which can create or contribute to the patient's pelvic pain, dyspareunia and abnormal function of the pelvic area.

As a fellowship trained specialist in Female Pelvic Medicine and Reconstructive Surgery, I have personally treated many women for complications related to transvaginal mesh repairs for pelvic organ prolapse and urinary incontinence. I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common mesh-related complications that I have personally seen are pelvic pain, pain with intercourse, pain with movement, pain with sitting, painful scarring of the vagina and pelvic floor muscles and tissues, painful scar bands or scar plates in the vagina, pain radiating into the groin, buttocks and thighs, paresthesias in the groin, buttocks and thighs, non- healing surgical scars, mesh exposure, mesh erosion into the pelvic organs, vaginal shortening and strictures, chronic inflammation of tissue, wadding or bunching up of the mesh in the vagina, and nerve entrapment. .

C. Findings specific to Naomi Larson related to her total Prolift implantation

My opinions as described below are based on my training, my extensive clinical experience in the field of female pelvic medicine and reconstructive surgery and my knowledge of the body of literature that pertains to my field.

In determining the cause of a specific injury it is necessary to "rule in" potential causes of the injury and then by process of elimination "rule out" the least likely causes to arrive at a most likely cause. This process is known as creating a differential diagnosis. I have formed a differential diagnosis where I have considered all possible etiologies of the Plaintiff's symptoms. I then created a hierarchy where I ruled out or deemed less likely certain potential causes. I have used this methodology in arriving at my opinions in this case which I hold to a reasonable degree of medical certainty.

First, I created a timeline of the patient's medical history both before and after her implant surgery. In this case, the patient had a history of adominal/pelvic surgeries prior to Prolift

implant including four cesarean sections, a laparotomy for a retained placenta, a right oophorectomy for an ovarian cyst 2002, a total abdominal hysterectomy 2005, hernia repair 2005, appendectomy 1984 and a laparoscopy with lysis of adhesions in 2006. Her pre-existing conditions also included depressive disorder with some anxiety, smoking, endometriosis, migraine, anemia from acute blood loss, dyspareunia, cystocele, rectocele, insomnia, obesity, pelvic adhesive disease and pelvic pain. She did not fall into the IFU's contraindicated class of "infants, children, pregnant women, or women planning future pregnancies".

In considering the cause of Ms. Larson's pelvic pain and dyspareunia, I first ruled in the mesh as a potential cause because of the related symptoms which began almost immediately after the mesh implantation surgery. I relied on documentation of her treating physicians and other health care providers to develop a medical history timeline for Ms. Larson and its relationship to these complaints.

The next step in my analysis was to rule out the other potential causes for her symptoms. On initial presentation to Dr. McNelis, Ms. Larson reported deep dyspareunia however the nature, quality and description of her symptoms were different before the implant surgery. The deep dyspareunia prior to her implant surgery was thought to be due to her known adhesive disease and addressed by Dr. McNelis during the same operation where she implanted the Prolift via adhesiolysis and placement of Interceed as an adhesion barrier. The patient's symptoms changed after the Prolift implant surgery. After the implant surgery, Ms. Larson first had symptoms from mesh exposure/erosion and then, as she healed into the mesh, she developed reproducible point tenderness symptoms from scarring and contracture of the mesh with palpable areas of stricture and banding.

Ms. Larson presented to Dr. McNelis with pink vaginal discharge and feeling exposed mesh. She was found to have mesh exposure and a small vaginal stricture. At the time of the first revision surgery, which was six weeks from the initial implantation procedure, she was noted to have two areas of mesh exposure/erosion. Had she not had mesh placed she could not have presented with bleeding and mesh exposure/erosion. The patient then saw Dr. McNelis 8 weeks from her initial implant surgery. She and her husband tried to have but it felt like he was "hitting" something which hurt. She was noted to have "some tenderness around area of right apical vaginal incision with some induration in this area" so Dr. McNelis recommended vaginal dilators "to help soften scar tissue" and refraining from sexual relations. Ms. Larson then saw Dr. McNelis 14 weeks after the initial Prolift procedure, 7 weeks from her first revision surgery, with dyspareunia both with the dilators and sexual relations. On exam, she had a palpable discrete area of the upper right vagina that was tender as well as a palpable tender band of tissue. Ms. Larson underwent her second mesh revision surgery to address this area of tight banding on both sides of the vagina. Intraoperative as Dr. McNelis cut into the tender adhesive band at the upper vagina, she encountered the prolene mesh, excising about a 3 cm piece. Ms. Larson then saw Dr. McNelis two months after her second revision surgery, was initially doing well with dilators but after stopping for only 4 days her pain returned. Dr. McNelis again noted tenderness over the mesh along the posterior wall from right to left sacrospinous ligament and very tender in the right upper vagina thus recommending further revision surgery which the patient undergoes on 2/2/2009. During this procedure, Dr. McNelis attempted to remove all of the posterior vaginal

mesh. Her physical exam findings included a "4 cm band palpable across the upper third of the vagina" that was "causing some stricture in the upper vagina".

I did consider her pelvic adhesive disease as the cause of her current symptoms. As discussed above, the pelvic adhesive disease was addressed during the initial Prolift implantation surgery. While adhesions could potential cause dyspareunia and pelvic pain, they would not cause exposed mesh nor does this explain why mesh was consistently found in the areas of banding addressed each time Dr. McNelis reoperated on this patient. Furthermore, as mentioned early, the nature of the patient's symptoms changed after the Prolift implant procedure. The patient had known adhesive disease well before her implant procedure. She was familiar with her pain and discomfort from her adhesive disease and was even able to accurately identify when she developed pain different from her baseline as evidenced by her 9/27/2005 emergency surgery. Ms. Larson described to PA Hegg pelvic pain that "feels like when had retained placenta" in the "center pelvis" which was very tender to palpation. She was admitted to Buffalo Hospital where she emergently operated on. She was found to have an incisional hernia with infarcted fatty epiploica that was the source of her pain. In addition, even after her revision surgeries she continues to have rectal pain, pain with prolonged standing, heavy lifting and jarring movements all of which are likely related to the scarring around the residual mesh and mesh arms causing pulling and tugging of the nearby tissue. The pelvic adhesive disease could be a contributor to her dyspareunia and pelvic pain, however, the timing and description of her clinical symptoms make the Prolift mesh the far more likely. While Ms. Larson did have pelvic pain and dyspareunia prior to her Prolift surgery, the medical records are clear that those symptoms significantly worsened after implantation of the Prolift mesh. Given the timing and clinical presentation of the pelvic pain and dyspareunia, Prolift mesh is the cause.

I also considered and ruled out the other implants she had placed in the vagina, her Obtryx sling and Repliform grafts, as a cause of her current symptoms. Dr. McNelis did not attribute the Obtryx sling to any of Ms. Larson's injuries or symptoms. While this sling may be a contributor to pain she is having related to passage of mesh arms in the obturator space, the mesh load from the Obtryx sling is much less than the Prolift. In addition, this transobturator sling cannot explain the scarring and banding Ms. Larson had towards the vaginal apex, nor can it explain her current rectal symptoms. Dr. McNelis specifically identified areas of Prolift mesh causing pain on exam, not the much more distal transobturator sling. I also ruled out the Repliform grafts a cause of any of her injuries as there is no evidence in the medical record of any symptoms of the location of those grafts, or any removal of the grafts, unlike the Prolift. In fact Repliform is human cadaveric tissue that will remodel over time like Ms. Larson's own tissue so this cannot explain the constellation of her symptoms.

I also considered the fact that she resumed intercourse too early following her surgeries as a potential cause of her injuries. First, resuming intercourse too early would have no effect on the symptoms and physical exam findings which led to the second or third mesh removal surgeries because neither of those surgeries involved eroded mesh. In fact, intercourse would act more like a vaginal dilator preventing banding and stricture of normal human tissue. With regard to the first mesh removal surgery for areas of mesh erosions, transvaginal mesh placement with vaginal incisions is the largest risk factor for mesh exposure and erosion. In addition, Ms. Larson had bleeding as well as a pelvic abscess after the mesh placement that would have further increased

her risk for mesh exposure and the patient waited over 4 weeks prior to resuming intercourse. Looking at her entire clinical course, it is much more likely that the patient's risk for mesh exposure/erosion was that she had mesh placed vaginal than the act of intercourse. Again, resuming relations too early cannot explain all of her symptoms and physical exam findings since the implant surgery.

Based on my review of her medical records, while Ms. Larson had pelvic pain and dyspareunia prior to the implant surgery, after the Prolift surgery the description of her pain, locations, quality and severity of her symptoms changed. This changed pain and dyspareunia that she has been experiencing since her implant surgery cannot be explained solely by her pre-existing conditions. In my opinion, within a reasonable degree of medical certainty, this a direct result of having the Prolift mesh kit placed in the anterior and posterior compartment with arms through the obturator and ischiorectal fossa. Furthermore, since the surgery she is experiencing difficulty with standing and walking for prolonged periods of time which she did not have prior to the implant procedure. These symptoms are likely due to the contracture and scarring around the mesh pulling on the adjacent tissues and muscles. At her visit with Dr. Chase Sovell on 6/22/2012, he describes tenderness "to palpation of a spot over the lateral edge of the sacrum on the left side. This indicates some type of musculoskeletal pain as well." In essence he has described the location of the course of one of the Prolift arms and how it is causing her musculoskeletal pain. In addition, since her implant surgery, Ms. Larson has been having urinary urge type symptoms that did not exist prior to her implant surgery. While this patient also had a transobturator sling performed at the same time as the Prolift mesh procedure which can contribute to overactive bladder symptoms, these symptoms may be due to the Prolift mesh placed underneath the anterior vaginal wall affecting bladder contractility and the innervation to the sensory area of the bladder trigone. Even Dr. Gail Lundeen at the 9/20/2011 visit noted physical exam findings that suggest the mesh under the anterior wall has contracted leading to an "overcorrection of the urethrovesical junction angle". Her notes specifically go on to attribute Ms. Larson's rectal incontinence to her mesh surgery and subsequent revision surgeries. The rectal incontinence "is secondary to occasional loose stools without intervention as well as some disruption of nerve sensations having undergone multiple repetitive vaginal surgeries with mesh placement and mesh removal twice."

Thus, Ms. Larson's pre-existing conditions prior to surgery cannot fully explain the constellation of her postoperative symptoms. I considered each of her pre-existing medical conditions, including those listed above, as they related to her entire medical history and concluded to within a reasonable degree of medical certainty that they were not the cause of her listed injuries as they would not present so temporally related to her surgery and cannot explain the totality of her symptoms.

Naomi Larson's mesh erosions, mesh bands, chronic pelvic pain and dyspareunia is directly related to her mesh implantation surgery. Her persistent pelvic pain continues despite treatment with pain meds and 3 revision surgeries to remove eroded mesh and other portions of the graft by Dr. McNelis. She is also experiencing overactive bladder symptoms, rectal symptoms and musculoskeletal symptoms. Per her Plaintiff Fact Sheet, she now has difficulty with normal activities of daily living such as standing, activities with her children, travel, routine household chores such as cleaning the house, running, canoeing, tubing, and engaging in sexual intercourse.

Based on my education, training and experience in treating patients with incontinence/prolapse with or without mesh, educating physicians on prolapse surgery and mesh use, and my familiarity with published medical and scientific literature related to mesh complications, I am aware that armed mesh use in the vagina can cause significant pain and trauma to the nerves, muscles and tissues where the mesh is inserted and attached. Naomi Larson's records show that she has persistent pelvic pain and dyspareunia related to her mesh implant surgery as well as overactive bladder symptoms, rectal symptoms and musculoskeletal symptoms.

Based on the foregoing analysis, and based on my education, training, experience and knowledge, it is my opinion to a reasonable degree of medical certainty that the cause of her pelvic pain, dyspareunia is a direct result of the implanted Prolift prolapse mesh placed anteriorly and posteriorly. Due to the faulty and dangerous design of the product, as well as Ethicon's failure to adequately warn physicians and patients, Naomi Larson has suffered significant physical and emotional pain for over ten years. This has She has undergone three revision surgeries and may require future surgeries. Had this patient not been implanted with this product, she would not have suffered the emotional and physical loss to her quality of life nor the distress this has placed on her marriage. Furthermore, based on education, experience and review of medical literature it is highly unlikely that Naomi Larson even with further treatment including but not limited to medication, aggressive physical therapy, biofeedback, surgical intervention and nerve ablative procedures will have a complete resolution of her symptoms.

Had Naomi Larson and her surgeon Dr. McNelis known about and been adequately warned of the problems with Ethicon's products, specifically the Prolift, safer alternatives- including nonsurgical and surgical treatment options could been chosen for Ms. Larson. These safer, non-surgical alternatives included observation, pelvic floor physical therapy and pessary use. In addition, safer surgical interventions could have been chosen for her as well including, but not limited to, using her own native tissue for the prolapse repair procedure, the use of biologic grafts instead of synthetic mesh for her prolapse procedure, and the placement of mesh intraabdominally via a sacrocolpopexy for vaginal support. Had Ms. Larson been adequately forewarned about the risks of the Prolift mesh device, she may have elected to defer surgical intervention all together.

V. COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge $800/hour for case review and $1000/hour for depositions with a $1500 charge for depositions cancelled less than 48 hours before the scheduled date. I charge $1500/hour for expert testimony with a minimum of $2000 charge for scheduled testimony cancelled less than 48 hours before the scheduled date. Any payments for my work which exceed $54,000 goes to the University of California.

VI. OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

- *In re C. R. Bard, Inc. Pelvic Repair System Products Liability Litigation*
- *Tyson, et al. v. C. R. Bard, Inc.*
- *Crissman v. Ethicon*
- *Moe v. Ethicon*

VII. CONCLUSION

All opinions I have are to a reasonable degree of medical certainty. I reserve my right to amend my opinions if further information is provided in any form including but not limited to corporate documents, depositions, additional records, the expert reports of both Plaintiff and Defense experts and an independent medical exam, which I reserve the right to perform.

Signed this 8th day of October 2019.